
























**Structured Product Labeling (SPL) OTC Sub-team Teleconference**  
June 13, 2011, 1:00 – 2:00 pm ET  
**Call Summary**

**I. Call Attendees (based on emails received)**

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

-  Cheryl Blik, Teva Pharmaceuticals USA
-  Terry Brunone, GlaxoSmithKline
-  Amy Deuchler, Medline Industries, Inc.
-  Gilles Durot, i4i
-  Iris Feliciano, Tris Pharma
-  David Hale, National Library of Medicine (NLM) (guest speaker)
-  Michele Hewitt, Sandoz, Inc., Broomfield
-  Barbara Kochanowski, CHPA staff
-  Paula Markert, GlaxoSmithKline Consumer Healthcare (sub-team leader)
-  Wafa Nguyen, Qualitest Pharmaceuticals
-  Alison Rago, Intagras
-  Janet Riffitts, McNeil Consumer Healthcare
-  Dave Schilling, Chattem, Inc.
-  Howard Shatz, Data Conversion Laboratory, Inc.
-  Christie Simpson, Reckitt Benckiser, Inc.
-  Sandra Spiewak, Reed Technology & Information Services
-  Carl Strotz, Pfizer Consumer Healthcare
-  Tara Ryan, Prestige Brands, Inc.
-  Ann Vu, FDA CDER
-  Lynn Walks, i4i
-  Carey Wilson, Intagras
-  Robert Wirt, Allergan
-  Marcia Howard, CHPA staff (sub-team liaison)

**II. Next Standing Teleconference: July 11, 2011, 1:00pm ET (unless cancelled).**

Standing calls for 2011 will be held on the second Monday of each month only and will be cancelled as appropriate.

### III. Discussion

#### A. David Hale, NLM PillBox Initiative

- Hale reviewed the summary Q&A document previously circulated to SPL OTC sub-team members and also available on the SPL Working Group Wiki page.
- Additional questions addressed during the Q&A – *responses are summarized and do not reflect direct quotes or formal government responses*
  - Why do samples have to be unexpired?  
**Answer:** To avoid potential differences between unexpired and expired samples.
  - Are there future plans to include other dosage forms such as liquids?  
**Answer:** NLM would need to evaluate possible benefits of expanding the program to non-solid oral dosage samples to determine if a program expansion should be considered.
- Once the production version of PillBox is launched, all  $\beta$ -test images will be removed as they have not been validated by the manufacturers. The product version of PillBox will then contain only images verified by companies via SPL.
- Questions Post to Industry/Stakeholder Input to David Hale/NLM
  - To what level should participating companies be acknowledged on the NLM PillBox website, e.g., listing of companies who indicate their intention to participate, providing status of participating firms such as commitment to participate, samples submitted, etc.?
  - Should rulers and fiduciaries be included with the images and what is the level of importance?
  - What should happen to the Master image file?
  - What is the general time frame between when notice of participation has been submitted to NLM and samples should be received?
  - What other channels exist to promote the PillBox initiative?
- Additional feedback and/or questions regarding PillBox can be sent to David Hale directly ([PILLBOX@mail.nih.gov](mailto:PILLBOX@mail.nih.gov) or 301-496-3042) or via Marcia Howard ([mhoward@chpa-info.org](mailto:mhoward@chpa-info.org)).

#### IV. SPL Educational Forums/Information (*For Your Information*)

- A. **FDA Training Sessions:** Please visit the Data Standards Council website for details about upcoming agency training opportunities.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

- B. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)  
Telephone number: 877-423-2663  
PIN#: 240184

Please email Process Team co-leaders Terry Brunone ([Theresa.M.Brunone@gsk.com](mailto:Theresa.M.Brunone@gsk.com)) or Mary Beth Wilusz ([mary\\_beth\\_wilusz@merck.com](mailto:mary_beth_wilusz@merck.com)) if you want to get the email information.

SPL Working Group Wikipage: <http://spl-working-group.wikispaces.com/Drug+Listing> (no log-on or password needed).

- C. **SPL ER/DL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)

Please email sub-team co-leaders Patricia Cowall- Hanover ([COWALL-HANOVER PATRICIA L@LILLY.COM](mailto:COWALL-HANOVER PATRICIA L@LILLY.COM)) or Jessica Dunn Skorupski if you want to get the email information ([JSkorups@its.jnj.com](mailto:JSkorups@its.jnj.com)).

- D. **SPL Generics Sub-team calls:** Not currently holding regular calls.  
Please email sub-team leader Virginia Hogan if you want to get the email information ([Virginia.Hogan@tevausa.com](mailto:Virginia.Hogan@tevausa.com)).

- E. **Medical Products Sub-team calls:** Every other Thursday at 10:30 am EST  
Please email Sub-team leader Myron Finseth ([myron.finseth@medtronic.com](mailto:myron.finseth@medtronic.com)) if you want to join this sub-team.

Telephone Number: 770-657-9270  
Participant passcode: 745896

- F. **SPL Usage Discussion Group**  
Please email or call Terry Brunone ([Theresa.M.Brunone@gsk.com](mailto:Theresa.M.Brunone@gsk.com); +1-215-751-3210) or Gary Saner ([gsaner@reedtech.com](mailto:gsaner@reedtech.com); +1-610-731-7192) if you wish to join the discussion group.

- G.     **Homeopathic Sub-team** (*new sub-team; not replacing SPL OTC sub-team*)  
Next call: **June 23, 2011, 1:00 – 2:00 pm ET.**

Contact sub-team leader Travis Borchardt ([tborchardt@enzy.com](mailto:tborchardt@enzy.com)) if you wish to join this sub-team.

MDH/06-16-11

PL OTC Sub-team 13 June 2011 061611.doc  
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